

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Maurer, et al.
Serial No. TBA
Filing Date: Herewith
Title: Methods for Preparation of Lipid-Encapsulated Therapeutic Agents

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Washington, D.C. 20231

Sir:

Prior to the examination and calculation of fees due, please make the following changes:

In Claims:

Please cancel claims 1 through 12 and add the following claims:

13. A method for preparing fully lipid-encapsulated therapeutic agent particles of a charged therapeutic agent comprising the steps of
- combining a lipid composition comprising preformed lipid vesicles, a charged therapeutic agent, and a destabilizing agent to form a mixture of preformed vesicles and therapeutic agent in a destabilizing solvent, wherein said destabilizing solvent is effective to destabilize the membrane of the preformed lipid vesicles without disrupting the vesicles,
 - incubating the mixture for a period of time sufficient to allow the encapsulation of the therapeutic agent within the preformed lipid vesicles, and
 - removing the destabilizing agent,